DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-265/S-001

Ken Muhvich, Ph.D.
1818 Circle Road
Ruxton, Maryland 21204

Dear Dr. Muhvich:

Please refer to your supplemental new drug application, dated March 2, 2001, received March 7, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Infuvite *Pediatric* (Multiple Vitamins for Infusion).

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the labeling:

1. PACKAGE INSERT

At the end of the **DESCRIPTION** section, the following sentence has been deleted:

"Contains no more than 2000 mcg/mL of aluminum (combined vials 1 and 2)."

2. CARTON LABEL

The following sentence has been deleted from the outer (box) labeling:

"Contains no more than 2000 mcg/mL of aluminum (combined vials 1 and 2)."

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert dated March 2, 2001, and outer (box) labels dated March 2, 2001). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

However, we note that the submitted draft labeling does not comply with the formatting requirements for labeling in the Code of Federal Regulations (21 CFR 201.56). Therefore, at the next printing,

please position the WARNINGS section immediately after the CONTRAINDICATIONS section instead of after the PRECAUTIONS section as in the submitted draft labeling. The enclosed labeling incorporates this change.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-265/S-001." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and
Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE

cc:
Sabex Inc.
Attention: Leonor Ferriera
Director, Regulatory Affairs
145 Jules-Leger Street
Boucherville, Quebec, CANADA, J4B7K8

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Orloff

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